

Appl. No. : **10/807,643**
Filed : **March 23, 2004**

REMARKS

Following entry of the foregoing amendments, Claims 23 through 24, and Claims 27 through 61 stand pending in the present application.

Applicants would initially like to thank Examiners Schillinger and McDermott for permitting the personal interview between the Examiners and Applicants' representative on November 14, 2007. At the interview, the applied Solovay, (6,482,227), Fearnott et al. (6,565,597) and Hartley et al. (Pub. No. 2003/0199967) references were discussed, as well as Claims 23, 32, 46, 56 and 57.

In the Office Action mailed August 8, 2007, Claim 24 through 31, 33 through 45, 47 through 55 and 57 through 61 stand objected to because of the use of an indefinite article. These dependent claims have been amended herein, in a manner which is believed to resolve the objection.

Independent Claim 23, among others, was rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,482,227 to Solovay. Applicants attention was directed to items 80a and 80b (best seen in Figure 19 of Solovay) as disclosing Applicants' claimed "circumferential anchors", and Solovay's item 30 as disclosing Applicants' claimed "scaffold".

Solovay is directed to a profoundly different technology, involving a different anatomy, than Applicants' claimed invention. In relevant part, Solovay seeks to span a vascular aneurysm in the vicinity of the bifurcation between the aorta and the iliac arteries. Solovay discloses a modular system in which a "precursor stent 10" including a gasket member 30 is positioned in the infrarenal region of the aorta. Iliac branch grafts 80a and 80b are thereafter implanted such that an anatomically proximal end of each iliac graft is mounted within the stent 10 and sealed by the gasket 30 such that the entire aortic blood flow is diverted into and through the two iliac grafts. The distal end of each iliac graft is positioned within a respective iliac artery.

The clinical objective for Solovay is to divert the entire aortic blood flow through the iliac grafts from the infrarenal aorta into the iliac arteries, while preventing blood from flowing on the outside of the iliac grafts within the aneurysmal sac. *See, e.g.,* column 11 lines 27 through 31:

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The proximal ends of the stent-grafts are firmly attached to the iliac arteries 1 and 2. Thereafter blood will flow from the abdominal aorta 302 down into and through stent grafts 80(a) and 80(b) and into iliac arteries 1 and 2, thereby bypassing the aneurismal sac 304.

Applicants' claimed invention is neither disclosed nor suggested by Solovay. For example, Applicants' claimed prosthesis is configured such that following implantation, "a flow path is maintained in the main body lumen between the anchors and beyond the os opening".

Solovay discloses the opposite structure in the sense that the flow path in Solovay is isolated and exclusively limited to flow through the interior of each of the iliac grafts. This structural difference is a consequence of the profoundly different objectives of Applicants' claimed invention, in which optimizing flow through the main vessel lumen and in between anchors is desired, and Solovay in which eliminating flow in between the iliac grafts is desired and instead flow is diverted through the center of the tubular iliac grafts to isolate the main vessel lumen.

Accordingly, Applicants respectfully submit that Applicants' Claim 23 is neither identically disclosed by nor would have been obvious over Solovay.

Independent Claim 32 stands rejected under 35 U.S.C. § 102(e) as anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Solovay. Applicants respectfully submit that Claim 32, as amended, is neither disclosed nor suggested by Solovay.

Claim 32 is directed to a method for deploying a prosthesis across the os opening from a main lumen to a branch lumen. The method includes the steps of positioning a first prosthesis such that a scaffold lies within the branch lumen, and at least two circumferential anchors extend from the scaffold and into the main lumen. The circumferential anchors are deformed to circumscribe at least a portion of the main lumen wall, such that they "open a passage between the anchors". As discussed in connection with Claim 23, supra, Solovay fails to disclose a method of implanting a structure wherein blood flow is achieved between the "anchors" 80a and 80b.

In addition, method Claim 32 discloses the step of "deploying a second prosthesis within the passage through the anchors". Solovay fails to disclose or suggest deploying a second

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prosthesis through the anchors as recited in Applicants' Claim 32. Given Solovay's intended use environment, there would be no apparent reason to do so.

Accordingly, Applicants respectfully submit that Applicants' Claim 32 is neither identically disclosed by nor suggested by Solovay.

Independent Claim 46 stands rejected under 35 U.S.C. § 102(e) as anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Solovay. As discussed above, Solovay discloses a modular abdominal aortic aneurysm graft construct in which a stent is positioned in the infrarenal aspect of the aorta, followed by installation of a first and second iliac grafts which extend from the stent into the first and second iliacs, to divert blood flow from the aorta into the iliacs while relieving pressure on the aneurysmal sac. Solovay discloses structures for providing a seal to assure that the blood flow from the aorta enters the interior of the iliac grafts.

In contrast, Applicants' Claim 46 recites a "one-piece body including a radially expandable scaffold" for spanning a bifurcation and at least one anchor extending from an end of the scaffold. Rather than being a modular construct as disclosed in Solovay, Applicants' claimed prosthesis is one-piece structure in which the expandable branch vessel scaffold is preattached to the anchor, which is adapted to extend into the main vessel.

Applicants respectfully submit that Solovay neither discloses nor suggests the structure recited in Applicants' Claim 46.

Independent Claim 56 stands rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Publication No. 2003/0199967 to Hartley et al.

Applicants' Claim 56 recites a method for deploying a prosthesis, including, among other things, the method step of "providing a first prosthesis having a scaffold and at least two anchors", and positioning the prosthesis such that the scaffold lies within the branch lumen and the anchors extend into the main lumen. Harley fails to disclose or suggest this method.

Hartley discloses a different technology, in which a thoracic arch implant is positioned in the aorta such that it spans the ostia to the innominate, left carotid, and subclavian arteries. See Figure 7. Even accepting, arguendo, the Examiner's interpretation of items 121 as corresponding to Applicants' claimed anchors, it is clear that the Hartley implant remains entirely within the aorta, including the main body of the implant as well as the "anchors" 121. A second tubular prosthesis e.g. leg extension graft 127 may be positioned such that it spans from the branch

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vessel into the aorta. But the leg extension graft 127 is independent of the “anchors” 121. Accordingly, Applicants respectfully submit that Hartley fails to disclose Applicants’ claimed method in which a single prosthesis is provided having a scaffold and at least two anchors, and the prosthesis is positioned such that the scaffold is in the branch lumen and the at least two anchors extend into the main lumen to support the ostium.

Independent Claim 57 stands rejected under 35 U.S.C. § 102(e) as also anticipated by Hartley.

However, Claim 57 recites a method in which a single prosthesis is provided having a scaffold, and at least three anchors extending from an end of the scaffold. Hartley fails to disclose this structure.

In addition, Applicants’ claimed method recites positioning the prosthesis such that the scaffold is within the branch vessel and “the anchors extend along the wall of the main vessel and all point in an upstream direction”.

To the contrary, the “scaffold” from which the Hartley anchors 121 depend is positioned in the main vessel, rather than in the branch vessel as recited in Applicants’ Claim 57. In addition, the anchors 121 disclosed in Hartley all point in a downstream direction. This is the opposite of Applicants’ claim in which all of the anchors “point in an upstream direction”. This difference is attributable to the profoundly different intended use environments of Applicants’ claimed methods and devices, as compared to that of Hartley.

Dependant Claims 24, 27 through 31, 33 through 45, 47 through 55, and 58 through 61 depend either directly or indirectly from one of the independent claims discussed above. Accordingly, Applicants respectfully submit that the dependent claims are allowable over the prior art for at least the reasons discussed above in connection with the corresponding independent claim.

In view of the foregoing, Applicants respectfully submit that all pending claims in the present application are in condition for allowance.

Co-Pending Applications of Assignee

Applicants wish to draw to the Examiner’s attention to the following co-pending applications of the present application’s assignee.

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Serial Number	Docket No.	Title	Filed
10/584,968	ANVIL.001BNP1	PROSTHESIS FOR TREATING VASCULAR BIFURCATIONS	30-Jun-2006
11/744,796	ANVIL.1BNPC1	PROSTHESIS AND DEPLOYMENT CATHETER FOR TREATING VASCULAR BIFURCATIONS	04-May-2007
11/744,812	ANVIL.1BNPC2	PROSTHESIS FOR TREATING VASCULAR BIFURCATIONS	04-May-2007
11/744,802	ANVIL.1BNPC3	KIT FOR TREATING VASCULAR BIFURCATIONS	04-May-2007
11/076,448	ANVIL.001CP1	VASCULAR BIFURCATION PROSTHESIS WITH MULTIPLE THIN FRONDS	09-Mar-2005
11/190,514	ANVIL.001CP2	VASCULAR BIFURCATION PROSTHESIS WITH MULTIPLE LINKED THIN FRONDS	27-Jul-2005
11/249,138	ANVIL.001CP3	STEPPED BALLOON CATHETER FOR TREATING VASCULAR BIFURCATIONS	12-Oct-2005
11/603,338	ANVIL.001CP4	HELICAL OSTIUM SUPPORT FOR TREATING VASCULAR BIFURCATIONS	21-Nov-2006
10/965,230	ANVIL.003A	DELIVERY SYSTEM FOR PLACEMENT OF PROSTHESIS AT LUMINAL OS	13-Oct-2004
11/781,201	ANVIL.003DV1	PROSTHESIS FOR PLACEMENT AT A LUMINAL OS	20-Jul-2007
11/781,164	ANVIL.003DV2	SYSTEM FOR DELIVERING A PROSTHESIS TO A LUMINAL OS	20-Jul-2007

CONCLUSION

In view of the foregoing, Applicant respectfully submits that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolve

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12/5/07

By: Gerard von Hoffmann
Gerard von Hoffmann
Registration No. 33,043
Attorney of Record
Customer No. 20,995
(949) 760-0404

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